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Docket No. GEN-T111XC3D1
Serial No. 09/853,526Remarks

Claims 50-65 are pending in the subject application. By this Amendment, Applicants have amended claim 50 and added new claim 66. Support for the amendments and new claim can be found throughout the subject specification and in the claims as originally filed (see, for example, page 96, lines 13-18; and page 96, lines 28 through page 97, line 2). Entry and consideration of the amendments presented herein is respectfully requested. Accordingly, claims 50-66 are currently before the Examiner and favorable consideration of the pending claims is respectfully requested.

Claims 50-65 are rejected under 35 U.S.C. § 101 on the grounds that the invention is not supported by a specific asserted utility or a well-established utility. In addition, claims 50-65 are rejected under 35 U.S.C. § 112, first paragraph, on the grounds that one skilled in the art would not know how to use the claimed invention because it is not supported by a specific or well-established utility. The Advisory Action of May 2, 2005 has maintained the rejections under 35 U.S.C. § 101 because Applicants have not specifically defined a specific or substantial utility. The Advisory Action indicates that the specification as filed has not established a clear nexus between a neoplastic disease and the detection of the isoforms. In addition, the Advisory Action has maintained the rejection of claims 50-65 under 35 U.S.C. § 112, first paragraph, because the specification has not provided sufficient structure/functional relationship or provided sufficient representative species to represent the genus of sequences claimed.

In regard to the utility and enablement rejections, Applicants respectfully submit that the specification teaches that several isoforms of PG1 were identified, either from normal prostatic tissues or from a tumoral prostatic cell line (see column 42, lines 8-29 of U.S. Patent No. 6,265,546, which is the parent application of the subject application). Polypeptides of SEQ ID NOs: 4 and 5 correspond to full-length wild-type polypeptides, the mRNA of which is expressed in normal prostate (see column 42, line 17, of U.S. Patent No. 6,265,546). Expression patterns indicated that these proteins are localized in and/or around the nucleus of the cell (see column 44, lines 45-49, of U.S. Patent No. 6,265,546). On the other hand, the polypeptide of SEQ ID NO: 70 corresponds to a truncated isoform identified in the prostatic tumoral cell line LNCAP (see column 42, lines 20-25, of U.S. Patent No. 6,265,546). Expression patterns of this isoform indicate that it is localized in the cytoplasm of the cell (see column 44, lines 45-49, of U.S. Patent No. 6,265,546). Thus, it is

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respectfully submitted that the subject invention would have a specific, credible and substantial utility in the field of prostate cancer detection because one skilled in the art, in view of the teachings of the subject application, would be able to distinguish prostate cancer cells from non-cancerous prostate cancer cells on the basis of the localization of the various isoforms of the PG1 polypeptide within a sample of cells. Further, in view of these teachings, Applicants respectfully submit that one skilled in the art would know how to use the claimed invention and that the invention is, thus, enabled. Accordingly, reconsideration and withdrawal of the rejection under 35 U.S.C. §§ 101 and 112 is respectfully requested.

Turning to the written description rejection, Applicants respectfully assert that there is adequate written description in the subject specification to convey to the ordinarily skilled artisan that they had possession of the claimed invention. However, in an effort to expedite prosecution of the subject application to completion, Applicants have amended claims and now believe this issue to be moot. Accordingly, reconsideration and withdrawal of the rejection under 35 U.S.C. § 112, first paragraph, is respectfully requested.

It should be understood that the amendments presented herein have been made solely to expedite prosecution of the subject application to completion and should not be construed as an indication of Applicants' agreement with or acquiescence in the Examiner's position. Applicants expressly reserve the right to pursue the invention(s) disclosed in the subject application, including any subject matter canceled or not pursued during prosecution of the subject application, in a related application.

In view of the foregoing remarks, Applicants believe that the currently pending claims are in condition for allowance, and such action is respectfully requested.

The Commissioner is hereby authorized to charge any fees under 37 CFR §§1.16 or 1.17 as required by this paper to Deposit Account No. 19-0065.

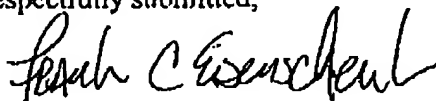
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Applicants invite the Examiner to call the undersigned if clarification is needed on any of this response, or if the Examiner believes a telephonic interview would expedite the prosecution of the subject application to completion.

Respectfully submitted,



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